Whitepaper

SKW Schwarz

Healthcare Compliance

20 questions and answers on the provision of medical equipment to physicians, medical practices and hospitals

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Healthcare Compliance (HCC)

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Medical equipment and instruments are constantly improving, becoming more advanced and more precise. However, innovation comes at a price. Purchasing modern equipment is often costly. Not always does the budget allow to pay the frequently high purchase prices, especially in the hospital sector.

In such situations, those operating medical equipment have an interest in receiving or using the equipment at no charge, or they prefer paying off the use by purchasing consumables for the equipment. At the same time, manufacturers interested in regular sales of consumables would be happy to accommodate their customers within their budget constraints on equipment usage. However, numerous pitfalls of healthcare compliance (HCC) lurk here, including possible criminal liability.
We explain which arrangements are (still) possible, what you should definitely not do, and how you can significantly reduce legal risks.

In **Part 1**, we explain which business models for medical equipment are problematic and which arrangements are still possible under the current legal situation.
In **Part 2**, we describe the potential consequences if the relevant legal rules are not observed.

Content

Part 1 on the provision of medical equipment: What is (still) possible, what is not? 10 questions and answers

1. What is the core problem with free equipment transfers?

→ In the past, it was a widespread business model for medical device manufacturers to provide medical equipment “free of charge” to hospitals and medical practices, expecting that in return they would purchase consumables for the equipment from the manufacturers who would then financed the costs of the equipment. Sometimes even today the rumor persists that this is a "standard market practice" and permissible.

In most cases, however, this is not the case: **the provision of equipment free of charge often violates Sec. 7 of the German Drug Advertising Act (Heilmittelwerbegesetz, short: HWG)**. Depending on the case, a violation of the **kick-back prohibition of Sec. 128 SGB V** may also be considered. For physicians, the acceptance of free devices or their loan may constitute a **violation of professional law** (Sec. 32 para. 1 of the Model Professional Code of Conduct for Physicians (MBO-Ä) or the corresponding professional regulations of the federal states (Bundesländer) in Germany).

Most importantly, such business models can lead to criminal liability. The criminal offenses of **bribery and corruption in the healthcare sector in Sec. 299a and Sec. 299b** of the German Criminal Code (Strafgesetzbuch, short: StGB) will frequently be fulfilled. Particularly in the outpatient sector, there may also be a substantial risk of criminal liability as fraud (Sec. 263 StGB). Please refer to Part 2 below for more details on the risks and consequences of violations of legal provisions.

2. Why does the provision of medical equipment free of charge usually violate Sec. 7 of the German Drug Advertising Act (HWG)?

→ The German Drug Advertising Act (HWG) applies to all forms of product-related advertising for pharmaceuticals, medical devices and a variety of procedures and treatments (Sec. 1 para. 1 HWG). Sec. 7 para. 1 sentence 1 HWG generally prohibits the use of gratuities and promotional gifts as a method of product-related sales promotion (see 3. below for exceptions). Since the terms "gratuity" and "promotional gift" are interpreted broadly, this also includes the provision of **medical equipment free of charge** with the aim of promoting the sale of other products (e.g., consumables for the equipment).

It does not matter if the customer actually becomes the owner of the equipment or if it remains the manufacturer's property. The **loan of equipment (in particular a permanent loan)** also constitutes a gratuity, namely in the form of the opportunity to use the equipment free of charge.

Example: A medical device company provides a biopsy gun to a physician free of charge as a permanent loan in the expectation that the physician will then also purchase the matching biopsy needles from the manufacturer of the gun. The price of the needles (consumables) is then used to "cross-finance" the biopsy gun provided free of charge. The provision of the biopsy gun free of charge constitutes a gratuity prohibited by Sec. 7 HWG in this scenario and is therefore illegal.

3. Are there exceptions to the prohibition of gratuities and promotional gifts under Sec. 7 of the HWG?

→ Yes, but only a few. Sec. 7 para. 1 sentence 1 Nos. 1 to 5 HWG provide for certain exceptions to the prohibition of gratuities. However, these are usually not applicable in the case of free provision of medical equipment.

Above all, it cannot be argued that the equipment provided free of charge is a kind of **"discount"** because Sec. 7 para. 1 sentence 1 No. 2 HWG only permits cash discounts (e.g., 10% cash discount on the purchase price) or discounts in kind of the same goods (e.g., "11 biopsy needles for the price of 10" or "If you buy 10 biopsy needles, you will receive one biopsy needle free of charge").

Due to the high value of the equipment, the free provision of medical equipment **usually cannot be classified as a customary accessory or customary secondary service** within the meaning of Sec. 7 para. 1 sentence 1 No. 3 HWG either.

4. What about short-term provision of free equipment for test purposes? Is that possible?

→ An exception is, nevertheless, the **short-term provision of equipment purely for the purpose of testing**. However, this exception may only be used to provide a physician with the opportunity to try out the device and to convince himself/herself of the functionality of the device in practice from a medical point of view. According to applicable case law, this does not constitute a product-related gratuity or promotional gift within the meaning of Sec. 7 HWG.

As a general rule, the testing period must be limited to three months; in exceptional cases, up to six months are possible. It is not permissible to just leave the device in the hospital or medical practice after the test period - it must then either be purchased, rented, leased, or collected again. A brief **agreement on the provision for test purposes** in writing or by email is advisable. As narrow limits apply here and much depends on the individual case, a testing program should not be set up without expert legal advice.

5. Can medical devices be provided free of charge for clinical trials?

→ In the context of clinical trials, **medical equipment can also be provided free of charge, but solely for the purpose of conducting the trial**. However, here again - as in the case of testing - some specific aspects and details must be taken into account. For example, the provision of equipment must actually serve the uniform and controlled collection of trial data in accordance with the study protocol - i.e., the clinical trial must not be a mere pretext for the free provision of equipment. Furthermore, the use of the equipment must be limited to the conduct of the clinical trial, excluding the use for any other purposes. Finally, the provision of equipment and its conditions should be recorded and agreed on by the parties in writing, preferably directly in the **clinical trial contract**.

6. Is it permissible to donate equipment to medical practices or hospitals (donation in kind)?

→ In principle, equipment can be donated to hospitals as a donation in kind if they are recognized as non-profit institutions. Donations to medical practices, on the other hand, are generally not permissible. However, even in the case of equipment donations to hospitals, strict requirements must be observed to ensure that the donation is not inadmissible within the meaning of Sec. 7 HWG:

Donations are generally **only permissible for charitable purposes**. The Medical Device Code of Conduct of BVMed lists the following admissible purposes in its Sec. 10 para. 1:

- Research and educational activities of scientific value
- Improvement of healthcare
- Improvement of patient care
- Education and training
- Charitable purposes

In addition, there must be **no connection** or dependence of the donation on any **sales transactions** or **procurement decisions**. Particularly if the company wishing to donate equipment also supplies the institution with products, the distinction between a permissible donation and an impermissible gratuity or gift for sales promotion purposes (violation of Sec. 7 HWG) can be difficult and problematic in individual cases. But even if, for example, an **association** or a **foundation** supporting a hospital receives a donation with which a physician has a connection, strict care must be taken to ensure that no criminal offense of corruption (esp. Sec. 299a, 299b StGB) is fulfilled, since donations to third parties for the purpose of influencing procurement decisions are also problematic from a criminal liability perspective.

Moreover, donations must always be made to the recipient institution as such, officially processed through the administration (**principle of transparency**) and properly documented (**principle of documentation**). They may be made only after clarifying the legal status of the recipient and only in return for a proper donation receipt (cf. Sec. 10 para. 2 and 3 of the Medical Device Code of Conduct). Under no circumstances may donations be made directly or personally to physicians or other healthcare professionals (HCPs) (Sec. 10 para. 4 of the Medical Device Code of Conduct).

Donations are only ostensibly an easy way to provide free equipment to medical institutions. In practice, such donations should always be examined very carefully, primarily because of the **risk of criminal liability for corruption**. Tax issues must also be reviewed and assessed.

7. How can a provision of equipment be structured if the customer does not want to or cannot pay the purchase price for the equipment immediately?

→ In "normal" cases involving the provision of equipment, none of the exceptions listed in questions 3 to 5 apply. As a general rule, this means that if a violation of Sec. 7 HWG is to be avoided, there must not be any free benefit at all. **Outside the exceptions mentioned above, the equipment may therefore not be provided free of charge, but only in return for payment.**

If the hospital or medical practice does not want to (or cannot) pay the purchase price immediately due to budget limitations, there are several possible arrangements which - if properly designed and implemented - are compliant with German law:

The simplest option is **rental or leasing of the equipment**. Here, the customer pays a monthly or annual amount in return for the use of the equipment.

Installment **purchase** or **combined purchase** and **rental models** also make it possible to spread the costs for the equipment or its use over a longer period.

It is important here that the rental or leasing fee, or the purchase price installment to be paid always corresponds to the so-called "**fair market value**". The price paid for the use of the equipment must reflect the fair market value of the usage. Excessive discounts or deductions are considered to be an indication of a subsidy component and thus of a gratuity element in the pricing. The consequence is then again a violation of Sec. 7 HWG.

Example: (real court case) A discount of 72% on the list price suggests that the price is only symbolic in nature and includes in fact (at least partially) a gratuity. If the supplier is then unable to prove that the price nevertheless still constitutes fair market value and that, despite the high discount, it still achieves an economically reasonable margin above the cost price, it must be assumed that the offer violates Sec. 7 HWG (Cologne Higher Regional Court, d.d. February 23, 2011 – docket No. 6 W 2/11 – “Dental scanner”).

8. Does this mean that medical equipment and instruments can no longer be placed in consignment storages?

→ Consignment storages are warehouses of the manufacturer or supplier that are located in the vicinity or directly at the customer's premises. Outside of emergency care, however, there is a general **ban on the consignment storage** of medical devices (Sec. 128 para. 1 of the German Code on Social Security, Book No. 5 (Sozialgesetzbuch V, short: SGB V). In hospitals in particular, consignment storages of medical devices that are needed to care for patients, especially in emergencies, are common and generally permissible.

However, this does not mean that manufacturers can also place medical equipment and instruments in consignment storages at will, from which the physicians of the hospital or medical practice can then remove and use them as needed free of charge. Even the possibility of **using a device free of charge** usually constitutes a **prohibited gratuity** (see question 2).

However, it is possible to allow the **use of equipment and instruments from a consignment storages for an adequate fee**. For example, business models can be designed in which the medical practice or hospital pays a fee for each individual use (**"pay per use"**). If necessary, such a fee can also be included in a **package offer** consisting of consumables and the (paid) use of equipment (see question 9 below). Exceptional cases are also conceivable in which the free use of a device or instrument from a consignment stock can be a **customary ancillary service** within the meaning of Sec. 7 para. 1 sentence 1 No. 3 HWG, which is not covered by the prohibition of gratuities and promotional gifts.

Since much depends on the individual case, it is necessary to carefully examine each arrangement and to find an appropriate solution for each case.

9. Are there still legal ways to finance the provision of medical equipment with the purchase of consumables?

→ Yes, there are. However, it is also important that the hospital or medical practice **pays for the use of the equipment** and that the impression that the equipment is provided free of charge is not created. In addition, there should be a **functional connection** between the equipment and the consumables. This is the case, for example, if only original consumables from the equipment manufacturer are compatible or approved for use with the equipment.

In this variant, an **combined offer (package offer)** can be designed, consisting of several components such as, for example, the provision of the equipment in return for payment of a customary usage fee ("fair market value"), and the purchase of a certain number or volume of consumables for the equipment.

Example 1: A manufacturer of an anesthesia machine enters into a contract with a hospital which provides for the rental of the machine and the purchase of 1,000 tubes per year at a specific total package price, whereas each package component is priced appropriately in accordance with fair market value.

Example 2: A medical device manufacturer makes a package offer for consumables in which a certain amount or percentage for the use of the associated equipment is included in a transparent manner in each purchase price for the consumables. A framework agreement with regulations on purchase quantities and accompanying contractual provisions (e.g., termination rights) ensures that the purchase of the consumables results in the actual payment of the rental price for the equipment in accordance with the fair market value principle.

10. What must be considered when designing combination or package offers?

→ Great care must be taken, however, when structuring such package offers (cf. question 9). There can be a thin line between a permissible package offer and an impermissible gratuity in certain cases.

It is permissible, for example, to grant a reduction (discount) on the total price of the combination offer compared to the sum of the prices of the individual components (cf. Federal Court of Justice, d.d. January 30, 2003 – docket No. I ZR 142/00 – “Garment Bag”). However, such a package offer must **not contain any "free items", especially not the free provision of equipment**. Creating the impression on the part of the recipient of the offer of a free component is already sufficient for the offer to become inadmissible. In addition, it must be ensured that the usage fee for the equipment is always actually paid and not just exists "on paper”.

Example of an impermissible arrangement: A medical device manufacturer offers a package deal consisting of dental products and a tablet (iPad) with software. The tablet is priced at EUR 730 (unit price) and the software at EUR 302 (unit price) in the total offer. A discount of EUR 1,032 is granted on the total price of this package. Since the discount is the same as the value of the tablet and software, it is evident from the customer's perspective that the tablet and software are free components of the package ("free items") and therefore gratuities.
For this reason, the package offer violates Sec. 7 HWG (Cologne District Court, d.d. May 22, 2014 – docket No. 31 O 30/14).
(real court case)

Many other aspects must be considered in the design of such business and contract models. For example, the offer must not be presented in a misleading way, must not unduly influence therapeutic decisions, etc. Offers and contracts for such package offers or combination offers should therefore always be legally examined on an individual basis before they are used in business.

Part 2 on the provision of medical equipment: What are the consequences of violations? 10 questions and answers

1. What are the consequences of violating Sec. 7 of the German Drug Advertising Act (HWG)?

→ Violations of Sec. 7 HWG regularly also constitute an act of unfair competition, Sec. 3a of the German Act against Unfair Competition (UWG), and may result in warning letters and legal action. In Germany, claims for **cessation** and **desistance** and for **injunctive relief** can not only be asserted by consumer associations and certain institutions, but also by competitors (Sec. 8 para. 2 UWG).

Competitors may then also be entitled to reimbursement of their legal costs (e.g. in the case of a justified warning letter, Sec. 13 para. 3 UWG). Claims for damages exist in theory (Sec. 9 UWG), but are irrelevant in practice because competitors usually cannot prove any concrete damage caused by a specific infringement of the HWG or UWG.

In addition, violations of Sec. 7 HWG are punishable as **administrative offenses**. **Fines of up to 50,000 EUR may be imposed for each individual infringement** (Sec. 15 para. 1 No. 4 and 4a, para. 3 HWG).

2. We have received a warning letter from a competitor for a violation of the HWG / UWG - what should we do?

→ If you receive a warning letter, you should **immediately seek expert legal advice**. The **deadlines are regularly very short**; in most cases, the response period is only one week. If you do not respond in time, the person or company issuing the warning can go directly to court and, for instance, apply for an injunction.

If the warning letter is justified, it can be advisable to sign adequate undertakings to avoid a hopeless legal dispute and the associated costs. Even then, however, it is advisable not to sign the undertakings attached to the warning without prior legal review. Quite often, these undertakings go too far. In such cases, signing modified (limited) undertakings is often the best approach, so that future advertising and sales activities are not unduly restricted without need. An expert lawyer for healthcare advertising law will also check this and give respective advise.

If the warning letter is unjustified, it should be rejected with detailed counterarguments (in case of doubt by a lawyer). This is because the person issuing the warning letter is required to submit the response to the court if he or she applies for an injunction in Germany. Under certain circumstances, it may also be advisable to file a so-called **protective writ** in order to proactively make one's voice heard in court. In the event of a rejection of an unjustified warning letter, there is usually even a claim for **reimbursement of the own attorney fees** against the person or company issuing the warning letter (Sec. 13 para. 5 UWG).

Since this always **depends on the individual case**, each warning letter for violations of the laws on the advertising of medical devices or against healthcare compliance requirements should always be examined individually by a lawyer specialized in this field before taking action or making any decision.

3. When is there a violation of Sec. 128 para. 2 and para. 5b SGB V?

→ Sec. 128 para. 2 SGB V prohibits so-called **"kick-backs"** to physicians admitted to the statutory health insurance system and to physicians in hospitals and medical facilities. A kick-back within the meaning of the law is any form of benefit (free advantage) that is provided in connection with prescriptions paid for by the statutory health insurance sytem.

However, Sec. 128 para. 2 SGB V only applies to kick-backs in connection with health aids within the meaning of Sec. 33 SGB V and the official Health Aid Directory. Health aids are items that are required in individual cases to support the success of a medical treatment by a replacing, supporting or relieving function, or to prevent a disability or to compensate for it. If, for example, a physician gets the opportunity to use medical equipment free of charge in connection with prescriptions of health aids, this is regularly a violation of Sec. 128 para. 2 SGB V. **Sec. 128 para. 2 sentence 3 SGB V explicitly lists the provision of medical equipment free of charge or below fair market value as a standard case of an unlawful kick-back violating Sec. 128 para. 2 SGB V.**

Example: An ENT doctor in private practice (admitted to the statutory health insurance system) receives a free iPad from a provider of hearing aids with software that illustrates how the hearing aids work. The iPad constitutes a free benefit. Hearing aids are health aids within the meaning of Sec. 128 para. 2 SGB V. Therefore, a presumed connection exists between the benefit and the prescription of benefits. The provision of the free software violates Sec. 128 para. 2 SGB V.

Sec. 128 para. 5b SGB extends the scope of application of the kick-back prohibition to "remedies" as defined in Sec. 32 SGB V. "Remedies" in this sense are services with a medical purpose that help to prevent or cure illnesses, prevent their aggravation or alleviate symptoms of illness (e.g. physiotherapy).

4. What are the consequences of violating Sec. 128 para. 2 and para. 5b SGB V?

→ A violation of Sec. 128 SGB V can have several - sometimes severe! - consequences. Pursuant to Sec. 128 para. 3 sentence 1 SGB V, the statutory health insurance system must **sanction violations** of Sec. 128 para. 2 SGB V. Contractual penalties may be imposed, and in the case of serious and repeated violations, even temporary **suspension from patient care in the statutory health insurance system** for up to two years (Sec. 128 para. 3 sentence 2 SGB V).

Furthermore, according to the case law of the Federal Social Court (d.d. July 2, 2013 – docket No. B 1 KR 49/12 R), violations of Sec. 128 para. 2 SGB V render the **respective remuneration claim of the physician against the statutory health insurance system void in total** (!). This means that the remuneration claim is not "only" reduced by the value of the kick-back which the physician received. Rather, the reimbursement claim for medical services related to the kick-back is "reduced to zero" overall.

This **complete elimination of the remuneration** claim may not only have considerable financial consequences - it also leads to a **risk of criminal liability**: If services are nevertheless billed to the statutory health insurance system in the knowledge of the kick-back (and thus the elimination of the remuneration claim), **billing the remuneration claim nevertheless can constitute attempted fraud, punishable under Sec. 263 of the German Criminal Code**. If the statutory health insurance system then makes a payment, this may even constitute completed fraud. This "chain reaction", which can lead from a violation of Sec. 128 para. 2 and para. 5b SGB V to the criminal offense of fraud, has been explicitly confirmed by the Federal Court of Justice (d.d. July 25, 2017 - 5 StR 46/17).

5. Can the provision of medical equipment free of charge be punishable under the anti-corruption provisions (Sec. 299, 299a, 299b of the German Criminal Code)?

→ If the recipient of the free (use of) medical equipment is a healthcare professional (HCP) who requires a state-regulated education for the practice of the profession or the use of the professional title - e.g., a physician - and if the provider of the equipment and the HCP agree, even subliminally, that the provider of the equipment shall be treated preferentially in competition in return, for example by way of purchase of consumables for the equipment (so-called **"unlawful agreement"**), then this may be punishable for all parties involved under Sec. 299a and 299b of the German Criminal Code (StGB).

The same applies if the HCP does not demand or accept this advantage for himself/herself, but for his/her **medical institution (e.g. hospital, medical practice)**. This is because the anti-corruption provisions of Sec. 299a and 299b StGB equate benefits to third parties with benefits to the "negotiator". It is sufficient that an HCP on the receiving side participates in the so-called "wrongful agreement" – he or she does not have to be the beneficiary himself or herself.

What is more: Especially if the equipment cannot be used at all without certain consumables of the respective manufacturer, such a wrongful agreement is often indicated by this fact. One reason is the consideration that no merchant has anything to give away, which is why the provision of equipment free of charge only makes economic sense if the value of the equipment is "recouped in return" (cf., the wording of the law) via the profit margin from the regular sale of consumables for the equipment. The fact that the HCP assumes that the free provision of the equipment is **subsidized** by the company and **ultimately financed** by the purchase of consumables, for example, does not mean that the HCP is exempt from criminal liability; on the contrary, it may even be the reason for it in the first place!.

6. What are the consequences of a violation of Sec. 299a and 299b StGB?

→ In the event of a violation of Sec. 299a and 299b StGB, all parties involved (sales staff, management, physicians, etc) face **imprisonment of up to three years or a fine**. To make matters worse, the **aggravating criminal offense of Sec. 300 StGB** is also fulfilled relatively easily: due to the frequently high price of equipment, there is often a "benefit of great value" (Sec. 300 sentence 2 No. 1 StGB). Even if this is not the case, it will usually be possible to establish a "commercial act" (Sec. 300 para. 2 No. 2 Alt. 1 StGB). And if at least three persons are involved in the deal - e.g. the sales manager, an account manager and a physician, or a sales employee and several physicians - these form a so-called "gang" from a criminal law perspective; then the aggravating offense is met for this reason alone. The consequence is an **increased range of potential punishment, namely imprisonment from three months to five years** (Sec. 300 sentence 1 StGB).

7. It is the hospital or of the medical practice that benefits from the free provision of the equipment, not the physician - does this not eliminate criminal liability?

→ Unfortunately, no. It is - as already mentioned under question 5 - **not necessary for** a criminal offense under Sec 299a and 299b StGB **that the HCP benefits himself or herself from the gratuity**. It is already sufficient if the HCP acts on the receiving side of the so-called "wrongful agreement". A benefit that then accrues to a third party - e.g., a hospital or a medical practice - in the form of free use of equipment is therefore also covered by criminal liability (compare the wording of the law: "advantage for oneself or a third party").

If the HCP is a shareholder of the recipient company, e.g. a partner in a partnership running a medical practice, he or she benefits indirectly from the gratuity due to less costs und thus higher profits of the partnership. In this case, there is no third-party benefit, but rather a benefit for the physician himself or herself. In the end, however, this is not important, since personal advantage and third party advantage equally lead to criminal liability, as said above.

8. My negotiating partner in the hospital is a business person in the purchasing department, not a physician - are free provisions of equipment permissible?

→ As a general rule: **No**. It is true, though, that in most of these cases the criminal offense of bribery and corruption in healthcare (Sec. 299a and 299b StGB) will not apply, since no HCP as defined by Sec. 299a StGB is acting on the "recipient side". However, criminal liability is still possible under the more **general anti-corruption provision of Sec. 299 StGB** (bribery and corruption in commercial transactions).

It is therefore not possible to circumvent the criminal liability risks of free provision of equipment by having a non-HCP conduct the discussions and make the decisions on the side of the hospital or medical practice.

In the case of Sec. 299 StGB, the **aggravating offense of Sec. 300 StGB** also looms relatively easily (cf., question 6 on the effects). Therefore, in the end, there is often no real difference as to the risks of criminal liability if no HCP is involved on the receiving end.

9. Can't the risk be eliminated by compliance clauses in the contracts?

→ So-called **compliance clauses** are often found in cooperation agreements between medical device providers and hospitals or medical practices. These state that the parties agree that no expectation of certain sales transactions or preferential treatment is associated with a certain service of the provider. Would it therefore be possible to exclude the risk of criminal liability by using such a clause in the case of free provision of equipment?

Unfortunately, this does not work. It is true that such a clause "on paper" is exactly the opposite of the so-called “unlawful agreement”, which is a prerequisite for criminal liability under Sec. 299a and 299b StGB. However, as is well known, "paper doesn’t blush”. If there is evidence that the provision of equipment free of charge was nevertheless associated with an at least tacit agreement that in return, for example, consumables for the equipment would also be purchased accordingly (the so-called "unlawful agreement", see question 5), then a compliance clause cannot prevent this behavior from being classified as an “unlawful agreement” giving rise to criminal liability.

10. I have discovered that my company has violated compliance requirements in the past. What should I do?

→ Healthcare compliance (HCC) regulations are sometimes very complex. Many delineations are difficult. As a result, there is unlikely to be a healthcare company that has never experienced compliance violations. However, a well-structured and established **compliance system** usually ensures that these are then only individual errors and isolated cases. These are usually far less problematic than systematic violations.

If you discover that HCC requirements may have been violated in your company in the past, **legal advice** should be sought. An attorney specializing in healthcare compliance should review the violation, evaluate it and make a recommendation on how best to handle it. The goal here will be to minimize the negative impact on the individuals or company involved, and to avoid a recurrence in the future. If necessary, a specialist in white-collar criminal law should also be consulted - especially if there is a risk of criminal liability.

Generally speaking, any infringements of compliance requirements identified in the past are always also an opportunity **to review** the company's **internal compliance system**, if necessary with the support of external experts. Violations are often an indication of gaps, errors or deficits in the compliance system. These should then be (systematically) remedied as quickly as possible. Often, the specialists will identify potential for improvement independently of the violation, which can then be implemented directly to optimize the compliance system.

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Oliver Stöckel has more than 15 years of experience with a wide variety of frequently highly complex issues in the Intellectual Property (IP) and Life Sciences & Health sectors. As an experienced litigator, he specializes in advising on IP disputes, proceedings before trademark offices, and infringement proceedings in trademark, patent, design, and copyright law. In competition law, he advises and represents clients in all types of disputes with competitors and is well versed in specific matters such as IP protection under competition law and environmental and pharmaceutical advertising.

He also enjoys vast experience in drafting, reviewing, negotiating, and enforcing R&D agreements as well as national and international licensing and distribution agreements, including in complex distribution structures and highly regulated business sectors. Additionally, Oliver Stöckel has particular expertise in pharmaceutical and medical device law, in compliance, in the areas of product liability and cooperation, as well as in issues relating to IP in the Life Sciences & Health sector.

About SKW Schwarz

SKW Schwarz is an independent law firm with about 130 lawyers, four offices, and a common claim: We think outside the box. In a world where everything is in motion, you need legal advice that recognizes change as an opportunity. That keeps on going where others have come to an end. That is just as passionate about complex issues as it is about new technologies, new markets, and new challenges.

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